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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,462	02/05/2007	Ryuji Ueno	Q76937	1105
23373 7590 06/09/2010 SUGHRUE MION, PLLC 2100 PENNSYLVANIA AVENUE, N.W. SUITE 800 WASHINGTON, DC 20037				
EXAMINER CARTER, KINDRA D				
ART UNIT		PAPER NUMBER		
1627				
NOTIFICATION DATE		DELIVERY MODE		
06/09/2010		ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

sughrue@sughrue.com  
PPROCESSING@SUGHRUE.COM  
USPTO@SUGHRUE.COM

### Office Action Summary

**Application No.**

10/567,462

**Applicant(s)**

UENO ET AL.

**Examiner**

KENDRA D. CARTER

**Art Unit**

1627

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 10-13 and 17-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 and 14-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/S5108)
- Paper No(s)/Mail Date 3/11/10/1/29/10
- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

The Examiner acknowledges the applicant's remarks and arguments of March 11, 2010 made to the office action filed December 11, 2009. Claims 1-20 are pending. Claims 1-8, 10-13 and 17-20 are withdrawn. No claim amendments were made. Claims 9 and 14-16 are examined on the merits in light of the Applicant's species election of 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF $2\alpha$  isopropyl ester in the reply filed on September 17, 2009.

The Declaration was fully considered but was not found persuasive to overcome any of the rejections.

In light of the abandonment of application 11/794,120 the obviousness double patenting rejection is withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection over Johnstone and Skuballa et al. were found not persuasive, thus the rejection is upheld.

Due to no new amendments to the claims and the Applicant's arguments not being persuasive, the previous 35 U.S.C. 103(a) rejection is repeated below. The Examiner has addressed the Applicant's arguments and Declaration below.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 and 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone (US 6,262,105 B1) in view of Skuballa et al. (US 4,088,775).

Johnstone teach that prostaglandin  $\text{PGF}\alpha_2$  compounds stimulate hair growth (see abstract and column 9, lines 1-55). Particularly,  $\text{PGF}\alpha$  analogues stimulate cell surface receptors, which activate a family of protein kinases that are fundamental in cell growth (see column 8, lines 19-27).  $\text{PGF}\alpha$  analogues also alter tensegrity that can

direct induction of DNA replication and stimulate cell division, prevention of apoptosis and prolong the hair cycle. By increasing the duration of the cell cycle, the interval in the anagen phase may be increased permitting hypertrophy of the follicles with longer and thicker hairs (see column 8, lines 29-33 and 50-59).

Johnstone does not teach the specific elected compound 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2 $\alpha$  isopropyl ester.

Skuballa et al. teach that compounds like 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2 $\alpha$  isopropyl ester (see column 3, lines 1-48) have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, it is generally known that the physiological effects of the prostaglandins are only of short duration in the mammalian organism as well as in vitro, since they are rapidly converted into pharmacologically inactive metabolic products. Thus, a physiologically inactive metabolite is formed by oxidation of the allylic hydroxy function on the C-15 atom (see column 2, lines 21-34).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teaching of Johnstone and 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2 $\alpha$  isopropyl ester because Skuballa et al. teach that compounds such as the elected compound have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see

abstract) because they are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2 $\alpha$  isopropyl ester to have similar activities as taught in Johnstone because it is a PGF2 $\alpha$  derivative, in which should have better activity as then other PGF2 $\alpha$  derivatives because of the teachings of Skuballa et al.

### ***Response to Arguments***

#### **Declaration**

Mr. Tabuchi demonstrates that the applicant's claimed compound, 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2 $\alpha$  ethyl ester does not have an effect to lower intraocular pressure, whereas the closest comparison compound from Johnstone, RESCULA (i.e. 13,14-dihydro-15-keto-20-ethyl PGF2 $\alpha$  isopropyl ester) lowers intraocular pressure (see page 3, results).

The Examiner has fully considered the declaration but does not find the results persuasive to overcome the rejections. Particularly, the comparison compound is not mentioned in Johnstone and thus can not be the closest comparison to the Applicant's claimed compound. Johnstone teaches several compounds that possess hair growth activity (see claim 9). Additionally, the comparison of activity should be between the stimulation of hair follicles to increase hair growth as Johnstone teaches and not over intraocular pressure.

#### **Rejection**

The Applicant argues that one skilled in the art would not use Applicant's elected compound to have similar activity as taught in Johnstone because the same compound does not have intraocular pressure effects like another PGF $2\alpha$  derivative (RESCULA), which structurally similar to the claimed compounds.

The Examiner disagrees for the same reason as given in for the arguments toward the Declaration. One skilled in the art would be motivated to use the Applicant's elected compound over the compounds of Johnstone because Skuballa et al. teach that compounds such as the elected compound have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, the compounds like the Applicant's elected compounds are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF $2\alpha$  isopropyl ester to have similar activities as taught in Johnstone because it is a PGF $2\alpha$  derivative, in which should have better activity as then other PGF $2\alpha$  derivatives because of the teachings of Skuballa et al.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kendra D Carter/  
Examiner, Art Unit 1627

/SREENI PADMANABHAN/  
Supervisory Patent Examiner, Art Unit 1627